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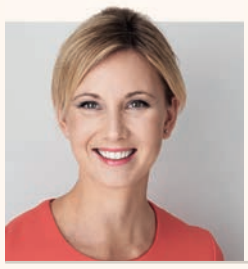
DENTAL TRIBUNE

The World's Dental Newspaper · Nordic Edition

PUBLISHED IN SCANDINAVIA www.dental-tribune.com VOL. 2, NO.1



INTERVIEW

In 2015, Swedish company TePe donated 50,000 toothbrushes and established the Eklund Foundation. Marketing Director Hanna Sjöström on giving back to society.

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THE POWER OF ELECTRONICS

Implementation of electronically based intra- and peri-oral therapeutic and diagnostic devices creates new possibilities for all kinds of novel applications.

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today SCANDEFA 2016

Read all about one of Scandinavia's largest dental events in our today specialty section included in this issue.

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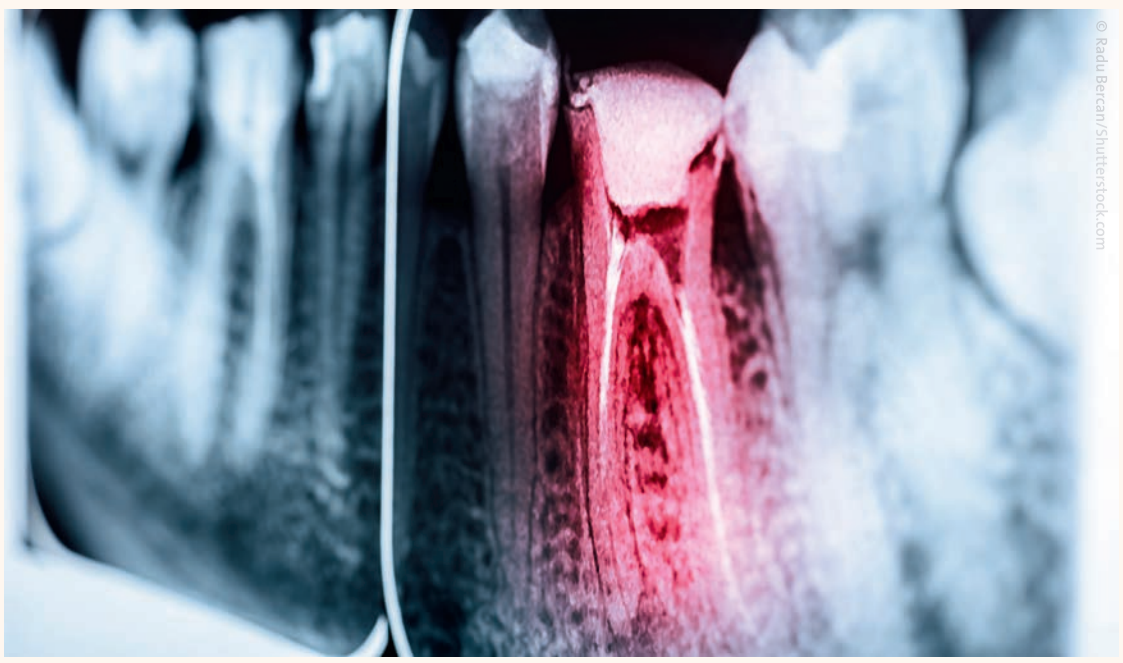
Many root fillings of poor quality

By DTI

GOTHENBURG, Sweden: A new survey has linked the quality of root fillings to the level of stress dentists experience in performing the procedure and the fee charged. Some dentists reported that "good enough" was often a more realistic goal than optimal quality in light of the complexity of root fillings and insufficient time allocated owing to the associated treatment tariff, among other reasons.



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A survey among Swedish dentists has established the potential for improving the quality of root fillings and thus reducing persistent inflammation associated with inadequate treatment.

According to the study, which was conducted as part of a doctoral thesis at the Sahlgrenska Academy, only half of all root fillings that are performed in the Swedish public dental service are of good quality. Moreover, more than one-third of root fillings show signs of apical periodontitis, which can lead to acute symptoms, such as pain and swelling, and may even spread and become life-threatening in some cases.

Aiming to investigate the reasons dentists accept technically poor root fillings, Lisbeth Dahlström, a senior dental officer and researcher at the Sahlgrenska Academy, conducted group interviews with 33 dentists from the Swedish public dental service.

The results showed that treatment was often associated with negative feelings, such as stress and frustration, and it was common for treatment to be performed with a sense of a loss of control owing to the perceived technical difficulty.

Another cause of dentists accepting poorer root fillings was that allotted time for treatment according to the fee charged was insufficient, participants reported.

▸ Page 2

Hormone controls sweet tooth

By DTI

COPENHAGEN, Denmark: Apparently, it takes more than a strong will to keep those with a sweet tooth away from a sugar overload in their diet, new research from the University of Copenhagen suggests. Aiming to determine whether sweet taste preference is in fact genetically biased, the scientists investigated the mechanism of the liver hormone fibroblast growth factor 21 (FGF21) in several mouse models.

"Based on these studies, and more, we can conclude that FGF21 decreases appetite and intake of sugar," said co-author Stephanie von Holstein-Rathlou, a master's student at the university. Consequently, FGF21 is the first identified liver-derived hormone that controls appetite, the scientists stated. Although these conclusions are largely still theoretical science, the researchers believe their discovery could potentially lead to drug therapy for obesity and diabetes.

Risks of snoring in children

By DTI

GOTHENBURG, Sweden: A new study from the Sahlgrenska Academy in Sweden has found that many parents underestimate the negative effects that breathing disturbances can have on their children's quality of sleep and life. Examining the prevalence of snoring and sleep apnoea in 754 children aged 11 and under, the researchers found that 4.8 per cent experienced sleep-disordered breathing symptoms several times a week. Despite pronounced snoring, only 31 per cent of these children had been in contact with a health care provider regarding their symptoms.

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"An obvious result of the study is that we must consider how parents are given information about the condition and where they can seek help," said Dr Gunnhildur Gudnadottir from the Department of Otorhinolaryngology at the academy.

"Children with persistent snoring often have a reduced quality of life. In particular, this applies to children who have sleep apnoea," Gudnadottir said. This is mainly due to the condition affecting sleep quality, which in turn can lead to daytime tiredness, concentration and learning difficulties, bedwetting and delayed growth.

The results of the study, titled "Healthcare provider contact for children with symptoms of sleep-disordered breathing: A population survey", was published in the March issue of the *Journal of Laryngology and Otology*.

First Nordic facial tissue transplant

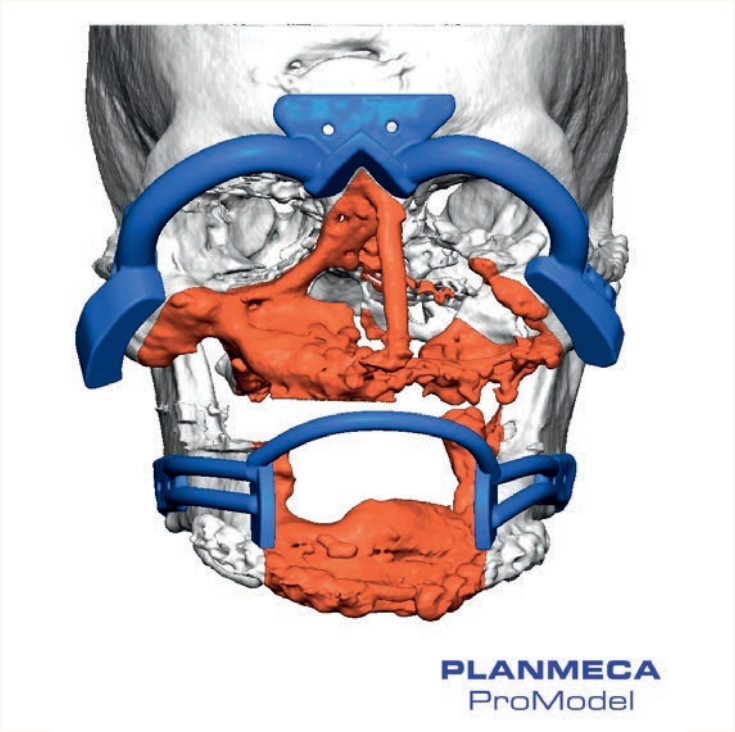
By DTI

HELSINKI, Finland: Finnish dental manufacturer Planmeca's ProModel technology has supported the first facial tissue transplant procedure in the history of the Nordic countries. The service, which designs and creates patient-specific surgical guides and skull models from CBCT/CT images, helped surgeons to significantly reduce operating time for the demanding procedure, which was performed at Töölö Hospital in the Hospital District of Helsinki and Uusimaa (HUS).

In addition to a decrease in surgical time, the ProModel technology was able to produce significantly more precise results compared with conventional methods, the surgical team stated at a press conference. Dr Jyrki Törnwall explained: "Based on literature, we know that it can take 3 to 4 hours to trim bones. In this particular operation, it took Patrik [Lassus] and myself under 10 minutes to place the transplant. This led to a drastic reduction in the duration of the surgery, while also significantly improving the accuracy of bone placement."

Using virtual surgery to simulate procedures is an increasingly important part of surgery today. "Surgeons and us engineers both see tremendous potential in this kind of collaboration," said Jani Horelli, CAD/CAM Design Manager at Planmeca. "The field continues to advance at a fast rate and it is very interesting to witness this evolution first hand. I am proud to be part of a highly skilled Finnish community of specialists. It feels meaningful to take part in improving the lives of people, who have encountered serious illnesses and disabilities."

Planmeca's collaboration with HUS spans nearly a decade. "Planmeca's role has been essential to our work for years—we have been able to utilise computer simulations to create saw guides, which allow us to saw at a specific orientation and to an exact depth, as well as remove facial structures, which we know match the donor, at a precise angle," said Törnwall, acknowledging the benefits of the company's 3-D services.



The facial tissue transplant procedure was planned preoperatively utilising Planmeca's ProModel technology, which designs and creates patient-specific surgical guides and skull models from CBCT/CT images.

Both HUS and Planmeca began planning for the operation already years before the surgery was carried out and this consisted of modelling donor tissue and determining how it matched the recipient, as well as simulating the operation together with the surgeons in advance. Following this, the components were designed and manufactured at Planmeca's headquarters and transported to the hospital, where they were taken directly to the operating room.

The extremely rare procedure, which was only the 35th of its kind in the world, entailed transplanting the patient's upper and lower jaws, lips and nose, as well as segments of the skin, midfacial and tongue muscles, and the nerves of these muscles. The surgery itself took 21 hours and included a team of 11 surgeons, 20 nurses and other medical experts. The first face transplant in the world was carried out in France in 2005.

European Consensus Conference releases update on dental implants

By DTI

BONN, Germany: The European Association of Dental Implantologists (BDIZ EDI) has released a new consensus paper that provides an update on short, angulated and diameter-reduced implants. The guidelines replace the 2011 guidelines, offer recommendations for the assessment of potential indications, and cover advantages and limitations of these types of dental implants.

Based on a working paper of the University of Cologne, the consensus paper was released after the 11th European Consensus Conference (EuCC), an annual meeting of an expert panel consisting of practitioners and academics held under the auspices of the BDIZ EDI, which aims to develop consensus on topics in implant dentistry and to draft the respective guidelines.

Regarding the classification of short, angulated and diameter-reduced implants, the EuCC agreed upon the following: Implants are usually referred to as short if their intrabony length measures less than or equal to 8 mm and their diameters of 3.75 mm and greater. Ultra-short implants are considered to be those with lengths less than 6 mm. Diameter-reduced implants can be defined as those with intraosseous diameters smaller than 3.5 mm for placement in sites with reduced alveolar ridge bone width. Implants with diameters less than 2.7 mm are referred to as mini-implants. In addition, the EuCC stated that mini-implants have an increased risk of loss and short mini-implants should be avoided.

According to the EuCC recommendations, the use of short, angulated or diameter-reduced implants in sites with reduced bone volume can be a reliable treatment option, given the risks associated with the use of standard-dimension implants in combination with augmentation procedures. However, the experts highlighted that the implant surgeon and the restorative dentist must have the appropriate training in the use of short and ultra-short implants. BDIZ EDI President Christian Berger said, "It is wrong to assume that short, angulated or diameter-reduced implants can be used to resolve one's own shortcomings in surgical technique. These implants were not developed for operators who have not (yet) mastered the external sinus lift and bone augmentation."

A printed version of the paper is available on request for €2.50 (including VAT, plus postage). The guidelines will also be published in the first 2016 issue of the *EDI Journal*, the BDIZ EDI's official member journal. It will therefore be available free of charge to members.

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"The dentist then finds they are facing a dilemma, to 'go back' to the treatment, to optimize quality, or to offer care within the framework of the compensation and, thus, risk accepting an incomplete root filling," Dahlström explained.

Regarding quality, the dentists interviewed reported uncertainty as to what constitutes reasonably acceptable quality. According to Dahlström, they often stated that "good enough" was a more realistic goal than optimal quality. However, despite the difficulties experienced, the survey also showed that the dentists wanted to provide good treatment and that they were very concerned about their patients, the researcher said.

In order to improve the quality of root fillings, Dahlström suggested measures such as increased opportunity for continuing education, time for discussion and exchange of experiences at the workplace, as well as investment in equipment that enhances treatment, shortens the time needed and improves visibility.

Approximately 250,000 root fillings are done in Sweden each year and it has been estimated that there are at least 2.5 million root-filled teeth affected by periapical periodontitis.

Dahlström defended her thesis, titled "On root-filling quality in general dental practice", on 4 March.

IMPRINT

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Published by DTI

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Drinking between meals may exacerbate dental erosion

By DTI

BERGEN, Norway: Rising consumption of sugary and acidic drinks has been found to be a key factor in the development and progression of dental erosion among children and adolescents. However, new research from the University of Bergen (UiB) indicates that, in addition to the amount consumed daily, when and the way in which soft drinks are consumed affects progression of erosive wear.

In the study, a team of UiB researchers evaluated the progression of dental erosion over a period of four years in a group of 175 adolescents aged 13–14. The prevalence of dental caries, as well as gingival and plaque status, was assessed in a clinical examination. Information on lifestyle factors, such as the method of drinking, frequency of physical activity, screen-viewing habits, as well as types and frequency of intake of certain dietary items, was obtained via questionnaires. These items included water, all kinds of acidic soft drinks, milk, yogurt, sour milk, tea, coffee, sweets, sour sweets, chewing gum, ice cream, popsicles, biscuits, snacks, cheese, as well as dried and fresh fruits.

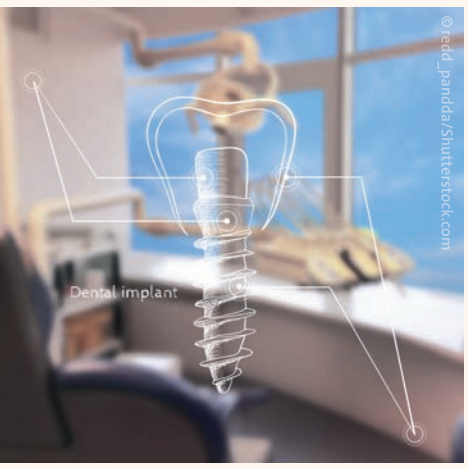
Over the four-year period, progression of dental erosion occurred in 35 per cent of the 2,566 tooth surfaces, and 32 per cent of the surfaces had deteriorated by one severity grade and 3 per cent by two grades. Overall, boys showed more severe erosion than did girls at the follow-up.

Dietary factors associated with greater progression of dental erosion included higher consumption of all drinks and sour candy, as well as drinks between meals, and lower intake of ordinary and sour milk, all of which are factors that have been shown to have a relationship with dental erosion in previous studies. Moreover, the habit of retaining acidic soft drinks in the mouth before swallowing was linked to higher progression of erosive wear.

According to the researchers, dental erosion was common in the study group, indicating a risk of severe erosive damage to permanent teeth even before adolescence. Dental health workers should therefore be made aware of this fact and regular screenings for erosion and recording of associated lifestyle factors should be performed, they concluded.

Dental erosion occurs when acid dissolves the hard tissue of the tooth. In its early stages, erosion strips away the surface layers of tooth enamel. If it progresses to an advanced stage, it can expose the soft pulp inside the tooth. In order to minimise the risk of tooth erosion and decay, experts recommend checking ingredients for acid additives, especially citric acid (ingredient number 330) and phosphoric acid (ingredient number 338).

The results of the study have been published online on 8 February in the *Journal of Dentistry* in the article "A 4 year prospective longitudinal study of progression of dental erosion associated to lifestyle in 13 to 14 year-old Swedish adolescents".



Straumann implants stand out

By DTI

GOTHENBURG, Sweden: New research has found that the effectiveness of implant therapy varied substantially between implant systems from different brands. In this study on the prevalence of peri-implantitis in a group of Swedish patients, Straumann implants showed the lowest odds ratios for the condition among all of the brands evaluated.

In assessing the prevalence of peri-implantitis and implant-related risk factors, researchers from the University of Gothenburg examined 588 patients who had received implant-supported therapy nine years earlier.

The study participants were randomly selected from the national data register of the Swedish Social Insurance Agency.

All of the participants underwent clinical and radiographic examination for typical indicators of peri-implantitis, including bone loss, bleeding, and increased pocket depth around their implants. Implants were grouped according to jaw and position, as well as by length, diameter and placement protocols. Furthermore, the investigators recorded bone augmentation procedures, including ridge and sinus augmentation.

ASTRA TECH (DENTSPLY Implants), Nobel Biocare and Straumann implants constituted 91 per cent of the 2,277 implants evaluated in the study. Of these, 96.6 per cent of the ASTRA TECH implants had a TiOblast surface, 98.3 per cent of the Nobel Biocare implants had a TiUnite surface, and all of the Straumann implants had an SLA surface.

Patients treated with Nobel Biocare, ASTRA TECH and other-brand implants showed significantly higher odds ratios for moderate/severe peri-implantitis than did patients treated with Straumann implants. However, as implant brands were unevenly distributed in the patient cohort, the findings regarding the prevalence of peri-implantitis according to brand of implant used cannot be generalised, the researchers concluded.

In addition to these findings, higher odds ratios for moderate/severe peri-implantitis were associated with patients presenting with periodontitis, patients with more than four implants, patients with implants placed in the mandible and with crown restoration margins positioned ffi 1.5 mm from the crestal bone at baseline, and with general practitioners performing the prosthetic therapy.

Overall, 45 per cent of patients in the study group presented with peri-implantitis, and 14.5 per cent had moderate/severe forms of the condition. The average amount of bone loss that occurred at implants affected by moderate/severe peri-implantitis corresponded to about 30 per cent of the initial bone support of the implant.

Peri-implantitis lesions are considerably larger and present with more aggressive features compared with lesions affecting teeth in periodontitis. Left untreated, the inflammatory condition can lead to implant loss.

The study, titled "Effectiveness of implant therapy analyzed in a Swedish population: Prevalence of peri-implantitis", was published in the January issue of the *Journal of Dental Research*.

“Prognosis is more important than a single technique”

An interview with Dr Giano Ricci, Italy

Dr Giano Ricci, Italy

In preparation for the 30th Annual Congress of the European Academy of Esthetic Dentistry (EAED) from 2 to 4 June in Copenhagen in Denmark, *Dental Tribune Nordic Edition* spoke with Dr Giano Ricci, President of the EAED. He has always been passionate about aesthetic and restorative dentistry and establishing good periodontal health. As a successful periodontist with a practice in Florence in Italy since 1972, he has been keen to keep up to date on the latest developments in dental aesthetics —many of which will be discussed during the meeting.

***Dental Tribune Nordic Edition:* What is the aim of the EAED, and what are the requirements for membership?**

Dr Giano Ricci: The academy was founded in 1986 in Geneva in Switzerland and received legal recognition in 1999. Today, we have 110 active members and 167 affiliates from all over the world. Our members have contributed to more than 1,000 publications in aesthetic and restorative dentistry. The promotion and advancement of this clinical field is our main goal. Membership of the EAED is a distinctive honour that is bestowed on a person who has notably contributed to the improvement of aesthetic dentistry through education, research or clinical practice. In order to become first an affiliate and then an active member, there is a four-step process involving attendance of our spring and autumn meetings and the successful presentation of a paper before a members' committee.

“Prognosis: The key for longevity” is the theme for this year's annual meeting in Copenhagen. Why is discussion about the long-term success of aesthetic and restorative treatment so important for dentists and patients?

Every dentist wishes to gain or maintain a good reputation. It is therefore essential to achieve long-lasting success with a good prognosis. Sometimes the use of a good technique does not automatically result in long-term success. However, patients who desire a good outcome are prepared to invest time, psychological effort and money to achieve this goal. It is natural that they wish to have the best possible treatment with a good prognosis in the long term.

The range of topics of the presentations include soft- and hard-tissue therapy, implant longevity, fixed and composite restorations, and functional and aesthetic treatment planning. Why have you chosen such an interdisciplinary approach to the meeting's theme?

It is almost impossible to solve complex cases without an interdisciplinary approach. Only by combining endodontics, prosthodontics, orthodontics and periodontics in a clinical collaboration is it possible to achieve good results. This is what functional and aesthetic dentistry is all about.

Could you give us a hint about your presentation? What do you plan to focus on in your opening remarks?

I will encourage all participants to interact with the speakers and to be receptive to engagement and debate. Communication is fundamental in dentistry. The meeting is an open forum with many experts and has been organised as such for a long time. All of our members, affiliates and guests have enjoyed the scientific and social parts of the EAED meetings. We have done our best to again organise a very interesting and exiting meeting.

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The 30th Annual Congress of the European Academy of Esthetic Dentistry (EAED) will take place from 2 to 4 June in Copenhagen.

> “...aesthetic materials will become progressively sophisticated and will mimic nature as closely as possible.”

EAED was founded in 1986. Back then, today's adhesive technologies, ceramics and digital smile design were barely thinkable. What advancements in technology and materials do you personally consider the most important in aesthetic dentistry?

Indeed, we have many more tools and materials today. For instance, adhesive technology allows us to be less invasive, as well as achieve good results. We have seen the same development with modern ceramics and digital dentistry. Modern ceramics have great versatility and provide a good long-term prognosis. Digital dentistry is arguably the most important recent development in aesthetic dentistry. Clinicians are guided by technology, which also helps less experienced dentists to achieve excellent results. I have been working with CAD/CAM and my prosthodontist son, Andrea, has endorsed digital smile design for his treatments. Digital design has helped clinicians to better understand the aesthetic and functional issues and plan accordingly. It has achieved higher treatment acceptance by patients and given patients a better understanding of the treatment the clinician wants to provide.

As we have recognised, the demand for improved aesthetics has led to the introduction of new ceramic materials and technologies in dentistry. Consequently, aesthetic and restorative dentistry has made substantial advancements. In your opinion, what will be the next steps in aesthetic dentistry in order to achieve long-lasting beautiful results?

The next step will be the improvement of results in terms of soft-tissue treatment. When surgery is needed, we will be able to minimise tissue contraction as much as possible. Stem cells and new molecules will increase soft-tissue response and speed up the healing process. Also, aesthetic materials will become progressively sophisticated and will mimic nature as closely as possible. We will also use more digital technology, which will become fundamental for treatment. It will be easier for the clinician to solve problems owing to this technique. In the future, its precision will increase, to the benefit of the patient.

You have announced the first EAED Innovation Award, sponsored by the Joerg Strub Foundation. Clinicians, postgraduate students, dental technicians and researchers can submit abstracts related to the field of aesthetic and reconstructive dentistry. Why did you decide to introduce this award after 30 years of existence?

The mission of the academy is to expand knowledge in dentistry with a focus on aesthetic dentistry specifically. After many years, we decided to present an award to support motivated colleagues and to promote research. Prof. Jörg Strub is a world-known researcher and clinician. His foundation aims to support and promote all fields of aesthetic and restorative dentistry and its related areas. Both the foundation and the Innovation Award seek to encourage and challenge young clinicians to pursue excellent aesthetic and restorative results and to explore new ways of treatment. Through the award, we also invite all professionals to become members and benefit from the expertise and meetings of the EAED.

Every year, the EAED meeting is held in a different European city. Copenhagen is very well known for its open culture and mild climate in the summer. What will the social programme for participants involve?

According to a recent United Nations report, Denmark has been declared the world's happiest country in 2016. Participants will certainly have the opportunity to find out if Copenhagen really is as charming as everyone says. During and after the meeting, we will have an exciting social programme, including a gala dinner at the National Gallery of Denmark, a welcome party and a run through the centre of Copenhagen. This will help all of us to appreciate the flavour of this wonderful city.

Thank you very much for the interview.

"We aim to facilitate oral hygiene on the go"

An interview with TePe Marketing Director Hanna Sjöström

Ever since its foundation in 1965, Swedish oral care company TePe has highlighted the importance of a close professional exchange with universities, institutes and dental professionals in developing its oral hygiene products. This philosophy culminated in the establishment of the Eklund Foundation for Odontological Research and Education last year, marking the company's 50th anniversary. *Dental Tribune Nordic Edition* spoke to TePe's Marketing Director, Hanna Sjöström, about the company's general approach of contributing to society.

Hanna Sjöström, Marketing Director at TePe.

Dental Tribune Nordic Edition: Could you tell us about TePe's commitment to research and education, most recently embodied in the establishment of the Eklund Foundation?

Hanna Sjöström: Ever since the Eklunds founded TePe in 1965, the company has had a special relationship with the dental community. After five decades of collaboration with universities, institutes and dental care professionals around the world, the Eklund family established the foundation as a way to show their appreciation by creating something that would contribute to knowledge and development within the odontological field for many years to come.

Could you explain the application process for funding that will start on 1 May?

From 1 to 31 May, applications will be accepted through the online form at *eklundfoundation.org*. During the summer, the applications will be evaluated by our reviewers, Dr Anna Nilvéus Olofsson, Manager of Odontology and Scientific Affairs at TePe, and Prof. Leif Dahlberg, head of the Division of Orthopaedics in the Department of Clinical Sciences, Lund, at Lund University. We welcome applications from all fields of dentistry and will particularly prioritise projects related to periodontology, implantology and cariology. Applications from postdoctoral researchers will be prioritised in the selection. The successful candidates will be announced in the autumn. This year, the foundation will distribute approximately €160,000 (DKK1.2 million) to one large project and a number of smaller projects.

> "Professional exchange is fundamental..."

Last year, TePe donated 50,000 toothbrushes to people displaced by the refugee crises. As a leading oral health provider, do you consider these kinds of actions a responsibility?

Nobody can do everything, but everyone can do something. As people in flight are in need of hygiene products, we felt that the donation would be one way of putting our vision of good oral health for everyone into practice.

Do you think that, generally, the industry should become more involved in societal commitments?

A locally anchored business like TePe relies on a good relationship with the business community and society. The support of our stakeholders is very important to us, and we earn that trust by contributing to positive developments wherever we operate.

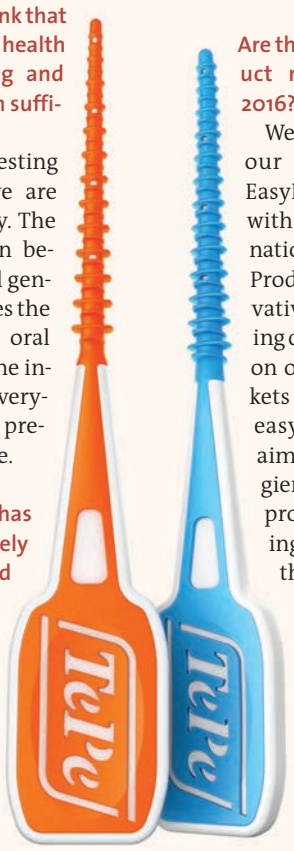
TePe's cleaning device EasyPick has just been awarded the international Red Dot Award in Product Design.

Your vision is for people to be able to keep their teeth for life, thus the company's focus on preventive dental care. Do you think that the importance of oral health for overall well-being and general health is given sufficient attention?

This is a very interesting discussion, which we are following very closely. The suggested connection between oral health and general health emphasises the significance of good oral hygiene and entails the insight that we have everything to gain from the prevention of oral disease.

As a company that has collaborated extensively with universities and scientific institutes in the past, how important is this kind of professional exchange?

Professional exchange is fundamental for TePe. Our in-house team of odontological experts, consisting of both dentists and dental hygienists, work in close dialogue with universities, institutes and dental professionals all over the world. Throughout the development of our products and educational materials, we incorporate research findings, as well as clinical requirements of the dental profession. This approach has earned us credibility and given us extensive knowledge, which we continue to build on. Our interdental brushes are a good example of our philosophy: once developed as a result of both research findings and clinical needs, and thereafter continuously improved, their efficiency continues to be supported by scientific studies.



Are there any events or product releases planned for 2016?

We are very pleased that our new product TePe EasyPick has been awarded with the prestigious international Red Dot Award in Product Design. The innovative interdental cleaning device will be launched on our international markets this spring. With this easy-to-use product, we aim to facilitate oral hygiene on the go. Another product worth highlighting is our newcomer in the toothbrush range, TePe Colour, which is designed to appeal to young people and put "more colour, more fun" into toothbrushing.

Thank you very much for the interview.

TRIOS scans most accurate and consistent

Study compares leading intra-oral scanning systems in terms of trueness and precision

BALTIMORE, USA/FREIBURG, Germany: A new study evaluating the accuracy of six leading intra-oral scanners in the dental market has found 3Shape's TRIOS to be both the most accurate and consistent performer of the scanners tested.

The study, which was conducted jointly by the University of Maryland in Baltimore and the University of Freiburg in Germany, aimed to compare the ability of intra-oral scanning systems of different brands to accurately scan a single molar abutment tooth *in vitro*. The analyses included the following six scanners: iTero (Align Technology), 3M True Definition (3M ESPE), PlanScan (Planmeca), CS 3500 (Carestream Dental), TRIOS and CEREC AC Omnicam (Sirona Dental Systems).

In order to compare the accuracy of each system, the investigators used an industrial-grade, highly accurate reference scanner to create a digital reference dataset for an acrylic dental model. A single trained, experienced dentist then scanned the acrylic model on three separate occasions using each of the six intra-oral scanning systems.

Trueness (accuracy) was defined by superimposing the three digital datasets over the reference dataset, with 3-D comparisons then performed. Precision (consistency) was defined by superimposing each dataset over the other two datasets obtained and then evaluating for 3-D deviations.

Of the 18 datasets analysed, the smallest deviations for the trueness measurements (± standard deviation) between the reference dataset and the various intra-oral scanner datasets were obtained from TRIOS (6.9 ± 0.9 µm), followed by CS 3500 (9.8 ± 0.8 µm), iTero (9.8 ± 2.5 µm), 3M True Definition (10.3 ± 0.9 µm), PlanScan (30.9 ± 10.8 µm) and CEREC AC Omnicam (45.2 ± 17.1 µm).

As for precision values, here too TRIOS was identified as the most accurate (4.5 ± 0.9 µm), followed by 3M True Definition (6.1 ± 1.0 µm), iTero (7.0 ± 1.4 µm), CS 3500 (7.2 ± 1.7 µm), CEREC AC Omnicam (16.2 ± 4.0 µm), and PlanScan (26.4 ± 5.0 µm).

"The TRIOS scanning technology, in combination with the wand design, seems to be beneficial for capturing high quality datasets with excellent trueness and precision values," the investigators said.

3Shape's intra-oral scanner TRIOS delivered the most accurate results when compared with other leading scanning systems in a recent study.

However, the results obtained do not provide any information about the quality of a fabricated restoration based on these digital datasets, the researchers stressed. Moreover, in an *in vivo* design, the outcomes might be different owing to the presence of blood, saliva, and patient movements, they concluded.

The study, titled "Evaluation of the accuracy of six intraoral scanning devices: An *in-vitro* investigation", was published in Volume 10, Issue 4, of the *ADA Professional Product Review*.

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Intra-oral and peri-oral electronic devices

An overview of current therapeutic and diagnostic systems

By Dr Andy Wolff, Israel

*Fig. 1: The TheraMon microsensor and a removable device to which it will be attached.—**Fig. 2:** TheraMon" reading station and microsensor, with a removable intraoral device.—**Fig. 3:** Lirón MAD.*

The functions and organ systems of the human body are, to a significant extent, controlled by electrical signals that travel along the nerves. Electronic medical devices are aimed at controlling biological processes and treat disease by modulating these electrical impulses. These devices may assist in the therapy of conditions that are currently untreatable or resistant to other therapy methods. They may deliver treatment with greater precision and fewer side-effects than conventional pharmaceutical products do.

In the last few decades, a variety of wearable electronic medical devices have been introduced to the market. Examples of such devices include neuro-stimulators, cardiac pacemakers, implantable cardiac defibrillators, cochlear implants and retinal implants. These devices are used to address a variety of conditions, such as brain disorders (including epilepsy, Parkinson's disease, traumatic brain injury, stroke, psychiatric disorders, etc.), chronic pain conditions (addressed through e.g. spinal cord stimulators), incontinence, cardiovascular disorders (including heart failure, angina and peripheral vascular disease), deafness and blindness.

A number of vital structures located in the oral cavity region are controlled by the nervous system, such as the salivary glands and the orofacial musculature. Given the largely proven diagnostic and therapeutic value of electronic devices, it is surprising that only a few intra- and peri-oral electronic medical devices have been released to the market. Moreover, in contrast to electronic devices that involve typically invasive procedures, such as pacemakers and spinal cord stimulators, the placement and even the wearing of devices in the intra- and peri-oral region are not invasive.

Nevertheless, it appears that the US Food and Drug Administration (FDA) has considered for many years that electronic medical devices carry an increased risk if worn in the head and neck area, compared with other body areas, such as the limbs. Thus, electronic medical devices for the head and neck area are generally classified by the FDA as Class III devices, which are the highest risk devices and are, therefore, subject to the highest level of regulatory control. However, recently the FDA has classified a small number of these types of devices as Class II devices, which are lower risk devices than Class III and require less regulatory control to provide reasonable assurance of the device's safety and effectiveness. Nevertheless, those devices have to meet special controls, which are requirements intended to address the unique concerns of specific types of devices. Some examples are as follows:

- On 11 March 2014, the FDA allowed marketing of an electronic device as a preventative treatment for migraine headaches (Cefaly, CEFALY Technology). The portable, battery-powered prescription device resembles a plastic headband worn across the forehead and atop the ears.[1] The user positions the device in the centre of the forehead, just above the eyes, using a self-adhesive electrode. The device applies an electrical current to the skin and underlying body tissue to stimulate branches of the trigeminal nerve, which has been associated with migraine headaches.
- On 8 July 2014, the FDA issued a final order classifying a transcranial magnetic stimulator for headache into Class II (special controls). The device delivers rapidly alternating, or pulsed, magnetic fields of brief duration that are externally directed at spatially discrete regions of the brain to induce electrical currents for the treatment of headache.
- On 20 November 2015, the FDA issued a final order to reclassify an electrical salivary stimulation system (SaliPen, Saliwell) as a Class II (special controls) device. Previously, it was a Class III device. This intra-oral device (more details later in the article) is restricted to patient use upon prescription of a dental practitioner or physician.
- On 22 January 2016, the FDA announced a proposed administrative order to reclassify cranial electrotherapy stimulator devices intended to treat insomnia and/or anxiety, from Class III to Class II (special controls).

Examples of three electronic intra- and peri-oral devices that are available are covered in the paragraphs that follow.

> "...it is surprising that only a few intra- and peri-oral electronic medical devices have been released to the market."

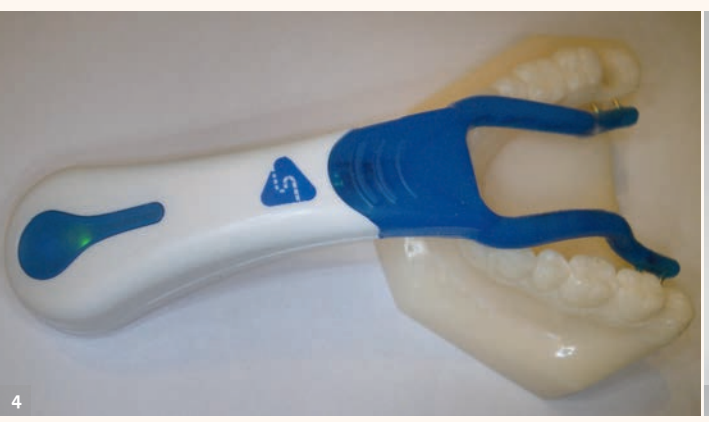
1. Intra-oral diagnostic device: Sensor for mandibular advancement devices

TheraMon (MC Technology) is a microchip specially designed to be embedded in removable orthodontic and dental sleep appliances.[2] According to the manufacturer, the sensor reports the temperature of the device and its surrounding area. This enables assessment of whether the sensor (embedded into the oral appliance) is being worn in the oral cavity or was outside of the mouth.

The TheraMon system consists of (a) a micro-sensor that measures and stores the temperature readings, that is wearing time data of the removable therapeutic device **(Fig. 1)**.; (b) a reading station that reads the memory of the micro-sensor using radio-frequency identification technology and transfers the data to a computer via a USB cable **(Fig. 2)**; and (c) assessment software that represents the wearing time in a diagram. TheraMon is a Class I medical product (lowest level of risk) that does not claim any medical, therapeutic or diagnostic functionality.

Sensors like TheraMon can be implemented in mandibular advancement devices (MADs), which are increasingly being prescribed as an alternative to the use of continuous positive airway pressure (CPAP) systems in the treatment of obstructive sleep apnoea. Studies have shown that MADs are preferred by patients and, thus, compliance with treatment may be greater than for CPAP. However, compliance with the treatment can be better measured in the CPAP system, as the built-in processor allows follow-up of the actual hours of use of the mask. In contrast, conventional MADs lack this control system and, thus, objective verification of compliance is not possible. Therefore, a microchip for thermal sensing that is inserted into a MAD can provide this missing ability to measure compliance objectively.

In a blind prospective clinical study of three months' duration, the safety and feasibility of objective measurement of compliance with MAD wearing was evaluated.[3] A Lirón MAD[4] **(Fig. 3)** equipped with a tem-



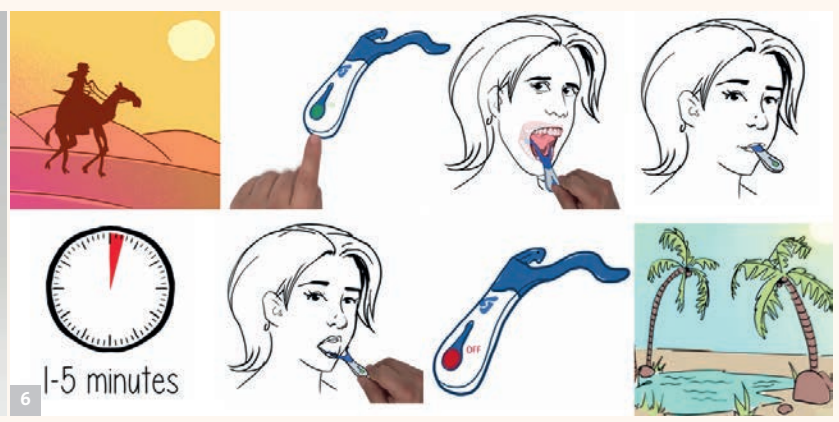


*Fig. 4: SaliPen device in place, reaching the lingual nerve region bilaterally.—**Fig. 5:** SaliPen device.—**Fig. 6:** SaliPen usage.*

perature micro-sensor was worn by 43 patients with an established diagnosis of respiratory sleep disorders. No adverse events related to the micro-sensors were recorded, nor were problems in reading of the compliance data. In this study, the mean time of Lirón use was 6.3±1.1 hours per day, with an 86 per cent compliance rate after a three-month follow-up. Statistical analysis found no differences between the data on objective and subjective use of Lirón. In conclusion, the results demonstrated the safety and the efficacy profile of the objective measurement of compliance with MAD wearing.

2. Intra-oral therapeutic device: Electrostimulation device to treat xerostomia

The commonly accepted clinical definition of xerostomia is the subjective sensation of dry mouth. The presence of xerostomia may indicate that salivary output is decreased or altered, placing patients at a higher risk of developing a number of oral diseases and complications. Increasing secretion of natural saliva is the most efficient means of relieving xerostomia, as natural saliva both alleviates dryness and contains essential dental decay-fighting factors and other components critical for oral health.[5] The prevalence of xerostomia in the adults' population is estimated at 10 per cent.

Salivary gland secretion is regulated by the autonomic nervous system, by means of the salivary reflex. The latter is composed of (a) salivary nuclei, located in the brain; (b) afferent nerve fibres, carrying stimuli (such as taste and mastication) from the peripheral to the salivary nuclei; and (c) efferent nerve fibres, conveying stimulatory signals from the salivary nuclei to the salivary glands. Application of electrical impulses to one or more of the three components of the salivary reflex increases salivary secretion.

Saliwell[6] has developed a line of intra-oral electrostimulation devices for which the principle of action is based on applying stimulatory signals in the vicinity of the lingual nerve, which is the main nerve controlling salivary function, as it carries both afferent and efferent fibres. Electrostimulation intensifies the impulses transmitted through the afferent and efferent nerve fibres, inducing the salivary glands to secrete more saliva. To this end, the device electrodes are placed at the lingual side, close to the mandibular third molar, an advantageous location owing to the close proximity to the lingual nerve, allowing effective stimulation by the use of lower voltage and current **(Fig. 4)**.

The most recently developed device (SaliPen) has an intra-oral stimulating unit and an extra-oral control unit **(Fig. 5)**.[7] The electrodes protrude at the end of two flexible silicone arms that are gently inserted underneath the tongue. In a typical usage profile, due to its long lasting effect, the device is worn about 4 times a day and about 4 minutes every time. **(Fig. 6)**.

A double-blind study, carried out at three medical centres in Europe, tested the device performance with short-term use, using a built-in moisture sensor.[8] As the primary outcome, measured oral dryness changes as a result of 10 minutes of wearing the device were assessed and compared between the usage of the device either switched on or switched off. Twenty-three patients with xerostomia due to different causes (primary Sjögren's syndrome, medications and idiopathic) were evaluated. The decrease in oral dryness (as measured by the moisture sensor) was significantly superior ($p < 0.0001$) when induced by the device in switched-on mode. No significant side-effects were observed.

In a multi-national randomised clinical trial, long-term (11-month) intra-oral electrostimulation was tested in a mixed sample of xerostomia patients (Sjögren's syndrome, radiotherapy, medication-induced, graft-versus-host disease and idiopathic).

In Stage I of the study, switched-on versus switched-off devices were compared, for a period of one month in a double-blind design (96 patients).[9]

In Stage II, immediately after Stage I, the xerostomia-relieving effects of the switched-on device only, were assessed in an open-label study (56 patients).[10]

The results of Stage I show that the patient-reported degree of oral moisture improved by 26 per cent when the device was switched on (with a statistical significance level of $p < 0.002$) versus an 18 per cent improvement when switched off. The results of Stage II show that the level of self-perceived oral moisture improved by 34 per cent ($p < 0.001$) and the amount of collected saliva increased by 25 per cent ($p < 0.001$) at rest and by 18 per cent ($p < 0.02$) during mastication. No severe or irreversible systemic or local adverse effects were observed at either stage of the trial.